UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/296,264	04/22/1999	JIM A. WRIGHT	032396-043	8152

7590 02/12/2002

Lisa A. Haile, Ph.D
GRAY CARY WARE & FREIDENRICH LLP
4365 Executive Drive
Suite 1100
San Diego, CA 92121

EXAMINER	
SCHMIDT, MARY M	
ART UNIT	PAPER NUMBER
1635	13

DATE MAILED: 02/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/296,264	Applicant(s) WRIGHT ET AL.	
	Examiner Mary M. Schmidt	Art Unit 1635	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED January 29, 2002, FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check only a) or b)]

a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.

b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *29 January 2002*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.

3. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search. (see NOTE below);

   (b) ☐ they raise the issue of new matter. (see Note below);

   (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☒ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

4. ☐ Applicant's reply has overcome the following rejection(s): _____.

5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

6. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):

   Claim(s) allowed: *none*.

   Claim(s) objected to: *17 and 18*.

   Claim(s) rejected: *1-16 and 19-22*.

   Claim(s) withdrawn from consideration: *none*.

9. ☐ The proposed drawing correction filed on _____ a)☐ has b)☐ has not been approved by the Examiner.

10. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

11. ☐ Other: _____

Continuation of 3. NOTE: The proposed amendments to the claims do not overcome or simplify the outstanding issues under 35 U.S.C. 112, first paragraph. Specifically, the claim amendments do not further limit the scope of the claims to a particular known target sequence described in the specification. Furthermore, the proposed new claims raise issues for further consideration under 35 U.S.C. 112, first paragraph, enablement and written description. For instance, the proposed claim amendment to claim 5 adds the limitation, "an anolog thereof" to the claimed composition, which must be newly considered for written desctiption issues. The methods as amended specify administration to humans and rodents, but must further be considered for scope of enablement issues. The proposed amendment therefore does not place the claims in further condition for allowance and will not be entered..

Continuation of 6. does NOT place the application in condition for allowance because: The claims are drawn to antisense compositions and methods of use of said antisense compositions which are not adequately described or enabled under 35 U.S.C. 112, first paragraph. The proposed amendendments to the composition claims specify the target gene as human or rodent, but do not provide specific SEQ ID NOS. to teach a representative number of the target sequences by way of sequence structure of the nucleic acids in possession of Applicant at the time the invention was made. Therefore the 35 U.S.C. 112, written description, rejection has not been overcome. In regards to the 35 U.S.c. 112, scope of enablement rejection, the proposed amendment adds new claims which read on administration of SEQ ID NOS:1-30 to any whole organisms for therapeutic purposes. Applicant also argues that the specification as filed teaches by way of example administration of antisense oligonucleotides to rodents which would have an expectation to correlate with the treatments of any whole organism as broadly claimed. In response, Figures 3 and 4 teach administration of specific antisense oligonucleotides via specific routes of administration to a rodent model. Due to the high level of unpredictability in the field of antisense treatment of whole organisms as argued previously, the rejection stands that one of ordinary skill in the art would have had to practice undue experimentation to design any antisense for the treatments broadly claimed. One of skill in the art would have also had to practice undue experimentation to useany of the proposed SEQ ID NOS:1-30 for the claimed therapeutic uses via any route of administration. As such, neither the proposed claim amendments nor the remarks filed overcome the outstanding 35 U.S.C. 112 issues .